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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/936,509 | 09/10/2001 | F. Ann Hayes | 2912-US | 4419 |
| 22932 | 7590 | 06/29/2004 | EXAMINER | |
| IMMUNEX CORPORATION LAW DEPARTMENT 1201 AMGEN COURT WEST SEATTLE, WA 98119 | | | O HARA, EILEEN B | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1646 | |

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,509

Applicant(s)

HAYES, F. ANN

Examiner

Eileen O'Hara

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-5 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Claims 1-5 are pending in the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deswal et al., Circulation., Vol. 96, No. 8, October 21, 1997, page I-323, abstract 1802, and further in view of Swedberg et al., European Heart Journal, ages 136-139, January 1999.

Claims 1-5 are drawn to a method of treating chronic heart failure in a patient comprising administering by subcutaneous injection a dose of TNFR:Fc at 5 mg/m² or 12mg/m² per dose up to a maximum of 25 mg per dose at least two times per week for a time sufficient to induce a sustained improvement over baseline.

Deswal et al. teach administration of TNFR:Fc to patients with advanced heart failure, wherein the dose is a single intravenous administration of 1-4 mg/m², and wherein the improvements were maximal 7-14 days after administration.

Swedberg et al. teach administration of enalapril for six months on average, to patients with severe heart failure, wherein improvement was sustained for at least 4 years after treatment.

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It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to optimize the conditions of administration of TNFR:Fc to patients with chronic heart failure, since Deswal et al. teach improvement of patients with advanced heart failure with a single low dose of TNFR:Fc, and the clinical trial of Deswal et al. was a preliminary study. Swedberg et al. is cited as demonstrating that it is desirable that any improvements in patients with heart failure be sustained. The skilled artisan would be motivated to optimize treatment regimens since chronic heart failure is a major health problem, and there would be a reasonable expectation of success since Deswal et al. demonstrated improvements in a preliminary clinical trial with TNFR:Fc, and since TNFR:Fc has been successfully used as a therapeutic in other conditions where excess TNF is a factor, such as rheumatoid arthritis.

Conclusion

3. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (571) 272-0887.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, se <http://pair-direct.ispto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

A handwritten signature in black ink that reads "Eileen B. O'Hara". The signature is written in a cursive, flowing style.

Patent Examiner